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2013 APR 16 AM 10: 49

April 15, 2013

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004



Dear 8(e) Coordinator:

Generic Name: [(disubstituted-carbomonocycle)-heteromonocyclyl]- alkylcarbomonocycle derivative

This letter is to inform you of the results of a repeat dose toxicity study with the above referenced R&D test substance. The test substance is an R&D substance and to the best of our knowledge not on the public inventory.

Repeat dose tolerability study of the test substance was tested in female SD rats. Three animals/dose level received 0, 300, 600 or 1000 mg/kg of test substance daily for 3 days. All rats were observed for clinical signs approximately 2 hours post dose. Clinical signs, daily body weights, food consumption, and gross pathology at necropsy were collected for each animal. All rats except one at 300 mg/kg/day were found dead on first or second day of dosing.

Clinical observations in the study included abnormal gait, splayed limbs and ataxia.

Gross observations in the animals found dead included discoloured lungs, fluid in the trachea, expanded lungs, and discolored trachea.

Sincerely,



Company Sanitized

Substantiating Claims of Confidentiality in Submissions to the TSCA §8(e) Office

Confidential Business Information Substantiation

1.	own	behalf? If the answer is no, please provide company name, address and one number of entity asserting claim.		
	[1		
2.	until a	hat period do you assert your claim(s) of confidentiality? If the claim is to extend certain event or point in time, please indicate that event or time period. Explain uch information should remain confidential until such point.		
	[]		
3.	Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.			
	[]		
4.	Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.			
		[]		
5.	they re	one outside your company has access to any of the information claimed CBI, are estricted by confidentiality agreement(s). If so, explain the content of the nent(s).		
	[]		
6.	Does the information claimed as confidential appear or is it referred to in any of the following:			
	a.	Advertising or promotional material for the chemical substance or the resulting and product[]		
	b.	Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this		

. .: .

		information as it appears when accompanying the substance and/or protime of transfer or sale); []				
	c.	Professional or trade	e publications; or			
	d.	Any other media or	publications available to the public or to your competitors.			
		If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.				
7.	regardi		gency, or court made any confidentiality determination ciated with this substance? If so, provide copies of such			
	[]					
8.	the CB relation your ar experti	Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately.				
	[]				
9.	Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?					
]]			
10.	Is this substance/product commercially available and if so, for how long has it been available on the commercial market? []					
	a.	If on the commercial commercially availa	I market, are your competitors aware that the substance is ble in the U.S.?			
	b.	•	ercially available, describe what stage of research and) the substance is in, and estimate how soon a market will be			

	c.	What is the substance used for and what type of product(s) does it appear in.
		[]
11.		ibe whether a competitor could employ reverse engineering to identically recreate bstance?
	[]
12.	Do yo	ou assert that disclosure of this information you are claiming CBI would reveal:
	a.	confidential processes used in manufacturing the substance; []
	b.	if a mixture, the actual portions of the substance in the mixture; []
	c.	information unrelated to the effects of the substance on human health or the environment? []
	If you be rev	r answer to any of the above questions is yes, explain how such information would realed.
13.	your c	de the Chemical Abstract Service Registry Number for the product, if known. Is company applying for a CAS number now or in the near future? If you have applied CAS number, include a copy of the contract with CAS.
	[]
14.		substance or any information claimed CBI the subject of FIFRA regulation or ing? If so, explain.
	[]